ADDITIONAL EXCEPTIONS TO IMPOSITION OF PENALTIES FOR PROVIDING INDUCEMENTS TO BENEFICIARIES OF CERTAIN HEALTH CARE PROGRAMS

OCTOBER 5, 1998.—Ordered to be printed

Mr. Archer, from the Committee on Ways and Means, submitted the following

REPORT

[To accompany H.R. 3511]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 3511) to amend title XI of the Social Security Act to authorize the Secretary of Health and Human Services to provide additional exceptions to the imposition of civil money penalties in cases of payments to beneficiaries, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

| I. | Introdu | ction |
|------|---------|-----------------------------------------------------------|
| | Α. | Purpose and Summary |
| | B. | Background and Need for Legislation |
| | C. | Legislative History |
| II. | Explana | ation of Provisions |
| III. | Vote of | the Committee |
| IV. | Budget | Effects of the Bill |
| | Ă. | Committee Estimate of Budgetary Effects |
| | В. | |
| | | tures |
| | C. | Cost Estimate Prepared by the Congressional Budget Office |
| V. | Other N | Matters to be Discussed under the Rules of the House |
| | A. | Committee Oversight Findings and Recommendations |
| | В. | Summary of Findings and Recommendations of the Government |
| | | Operations Committee |
| | C. | Constitutional Authority Statement |
| VI. | Change | s in Existing Law Made by the Bill as Reported |
| | 0 | • |

The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. AUTHORIZATION OF ADDITIONAL EXCEPTIONS TO IMPOSITION OF PENALTIES FOR PROVIDING INDUCEMENTS TO BENEFICIARIES.

- (a) IN GENERAL.—Subparagraph (B) of section 1128A(i)(6) of the Social Security Act (42 U.S.C. 1320a–7a(i)(6)) is amended to read as follows:
- "(B) any permissible practice described in any subparagraph of section 1128B(b)(3) or in regulations issued by the Secretary;".
- (b) EXTENSION OF ADVISORY OPINION AUTHORITY.—Section 1128D(b)(2)(A) of such Act (42 U.S.C. 1320a-7d(b)(2)(A)) is amended by inserting "or section 1128A(i)(6)" after "1128B(b)'
- (c) Effective Date.—The amendments made by this section shall take effect on
- the date of the enactment of this Act.

 (d) Interim Final Rulemaking Authority.—The Secretary of Health and Human Services may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment, in order to implement the amendments made by this section in a timely manner.

I. INTRODUCTION

A. Purpose and Summary

Current law prohibits medical facilities from making improper inducements in order to attract patients. Because of this, medical facilities have scaled back financial assistance programs which help patients, (e.g., programs to pay patient Medicare Part B and Medigap premiums) lest these programs be construed as improper inducements. H.R. 3511 would allow the Inspector General to develop criteria for making limited exceptions to the current fraud and abuse laws.

B. Background and Need for the Legislation

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) contained a number of provisions designed to toughen provision—Section abuse enforcement. One 231(h)(1)(C)(5) of HIPAA—prohibited medical facilities from offering patients any kind of inducement to receive services from any particular medical provider. This provision was designed to prevent kickbacks which the Inspector General reported was occurring in some circumstances.

Prior to the enactment of HIPAA, specialized medical facilities, such as dialysis centers, operated programs to help their patients afford medical treatment. Examples of these programs included paying patients' Medicare Part B premiums; giving patients free eye-glasses and other services designed to assist patients. The effect of the HIPAA fraud and abuse provision was to discourage medical facilities from offering programs to help patients lest these programs be seen as inducements for patients to receive services from the particular medical facility. This bill gives the Inspector General the authority to make exceptions and to establish safeguards which would permit an exception to the HIPAA provision.

H.R. 3511 affects the HIPAA provision in several ways: First, the Inspector General of the Health and Human Services Department could create exceptions—known as "safe harbors"—to the fraud and abuse rules so as to exclude specific practices from the HIPAA provisions. Second, H.R. 3511 would allow medical facilities to obtain

advisory opinions from the Inspector General. These opinions would provide legal and regulatory guidance to medical facilities as to whether payment of coinsurance or other premiums violates HIPAA's fraud and abuse provisions. Finally, H.R. 3511 would also give the Secretary of HHS interim final rulemaking authority which would speed up the process whereby these safe harbors and advisory opinions become effective.

The Committee recognizes that current law extends waiver authority for the anti-kickback provisions to certain entities and the Committee does not intend to alter the permanent status of any current waiver authority or permissible payment practice. The legislation is intended to affect new waivers granted and payment practices entered into after the effective date.

C. LEGISLATIVE HISTORY

On September 15, 1998, the Subcommittee on Health ordered favorably reported to the full Committee, by voice vote, H.R. 3511, without amendment. On September 18, 1998, the Committee on Ways and Means ordered favorably reported, by voice vote, H.R. 3511, as amended.

II. EXPLANATION OF PROVISIONS

1. AUTHORIZATION OF ADDITIONAL EXCEPTIONS TO IMPOSITION OF PENALTIES FOR PROVIDING INDUCEMENTS TO BENEFICIARIES.

Current law

Section 231(h)(1)(C)(5) of the Health Insurance Portability and Accountability Act (HIPAA) prohibits medical facilities from offering patients any kind of inducement to receive services from any particular medical provider. This provision was designed to prevent kickbacks which the Inspector General reported was occurring in some circumstances.

Explanation of provision

H.R. 3511 affects the HIPAA provision in several ways. First, the Inspector General of the Health and Human Services Department (HHS) could create exceptions—known as "safe harbors"—to the fraud and abuse rules so as to exclude specific practices from the HIPAA provisions. Second, H.R. 3511 would allow medical facilities to obtain advisory opinions from the Inspector General. These binding advisory opinions would provide legal and regulatory guidance to medical facilities as to whether payment of coinsurance or other premiums violates HIPAA's fraud and abuse provisions. Finally, H.R. 3511 would also give the Secretary of HHS interim final rule-making authority which would speed up the process whereby these safe harbors and advisory opinions become effective.

Reason for change

Prior to the enactment of HIPAA, specialized medical facilities, such as dialysis centers, operated programs to help their patients afford medical treatment. Examples of these programs included paying patients' Medicare Part B premiums; giving patients free eye-glasses and other services designed to assist patients. The ef-

fect of the HIPAA fraud and abuse provision was to discourage medical facilities from offering programs to help patients lest these programs be seen as inducements for patients to receive services from the particular medical facility. This bill gives the Inspector General the authority to make exceptions and to establish safeguards which would permit an exception to the HIPAA provision.

Effective date

Upon enactment.

III. VOTE OF THE COMMITTEE

In compliance with clause 2(l)(2)(B) of rule XI of the Rules of the House of Representatives, the following statements are made concerning the votes of the Committee in its consideration of the bill:

MOTION TO REPORT THE BILL

The bill, H.R. 3511, as amended, was ordered favorably reported by voice vote on September 18, 1998, with a quorum present.

IV. BUDGET EFFECTS OF THE BILL

A. Committee Estimate of Budgetary Effects

In compliance with clause 7(a) of rule XIII of the Rules of the House of Representatives, the following statement is made: The Committee agrees with the estimate prepared by the Congressional Budget Office (CBO) which is included below.

B. STATEMENT REGARDING NEW BUDGET AUTHORITY AND TAX EXPENDITURES

In compliance with clause 2(l)(3)(B) of rule XI of the Rules of the House of Representatives, the Committee states that the provisions in the Committee bill, if enacted, would increase Medicare spending by approximately \$20 million over the budget period Fiscal Years 1999–2003.

C. Cost Estimate Prepared by the Congressional Budget Office

U.S. CONGRESS, CONGRESSIONAL BUDGET OFFICE, Washington, DC, September 23, 1998.

Hon. BILL ARCHER, Chairman, Committee on Ways and Means, House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 3511.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Tom Bradley.

Sincerely,

JUNE E. O'NEILL, Director.

Enclosure.

H.R. 3511—A Bill to amend title XI of the Social Security Act to authorize the Secretary of Health and Human Services to provide additional exceptions to the imposition of civil monetary penalties in cases of payments to beneficiaries

Summary: H.R. 3511 would permit the Secretary of Health and Human Services (HHS) to exclude specific payment practices from the prohibition on offering inducements to Medicare or Medicaid enrollees to obtain services from a particular provider. The bill would also permit the HHS Inspector General to issue advisory opinions to individual providers concerning whether a specific payment practice violates the prohibition on offering inducements.

CBO estimates that enactment of H.R. 3511 would increase federal spending by \$2 million in fiscal year 1999 and by about \$20 million over the 1999–2003 period. Because the proposal would affect direct spending, pay-as-you-go procedures would apply. The bill does not contain any private-sector or intergovernmental mandates as defined in the Unfunded Mandates Reform Act and would not affect the budgets of state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 3511 is shown in the following table. Spending on Medicare benefits would increase by \$3 million in 1999 and \$25 million over the 1999–2003 period. Most of the new spending would be for services covered by Part B. About 25 percent of new Part B spending would be covered by higher premium payments by beneficiaries, which would amount to about \$1 million per year. Therefore, net Medicare outlays would increase by \$2 million in 1999 and \$20 million over the 1999–2003 period.

[By fiscal year, in millions of dollars]

| | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 |
|----------------------------------|-----------|----------------|---------|---------|----------------------------------------|----------------|
| CHANGES IN DIREC | T SPENDIN | IG | | | | |
| Medicare BenefitsPart B Premiums | 0 | $\frac{3}{-1}$ | 5 -1 | 5 -1 | $\begin{array}{c} 6 \\ -1 \end{array}$ | $-\frac{6}{1}$ |
| Total | 0 | 2 | 4 | 4 | 5 | 5 |

The costs of this legislation fall within budget function 570 (Medicare).

Basis of estimate: H.R. 3511 would give the Secretary and Inspector General the authority to grant exceptions to the prohibition on offering inducements to Medicare or Medicaid enrollees to obtain services from a particular provider. The proposal is intended to permit Medicare to establish a safe harbor to permit dialysis providers to subsidize Medicare Part B premiums or Medigap premiums for some low-income patients with end-stage renal disease (ESRD). CBO assumes the Secretary and Inspector General would use the authority for only that purpose.

Individuals of any age are entitled to Medicare Part A and eligible for Medicare Part B if they have ESRD and meet certain Social Security eligibility requirements. ESRD is fatal if not treated with either dialysis or a kidney transplant. About 80 percent of people with ESRD receive dialysis, which is covered by Part B. Therefore, nearly all beneficiaries with ESRD enroll in Part B.

Patients on dialysis incur high out-of-pocket costs. In addition to Part B premiums of nearly \$600 per year, dialysis patients' copayments for covered services furnished by dialysis facilities average between \$4,000 and \$5,000 annually. Nonelderly dialysis patients with limited financial resources and high medical expenses do not necessarily qualify for Medicaid.

CBO's analysis of data from the U.S. Renal Disease System indicates that about 8,000 people with ERSD die each year after voluntarily withdrawing from dialysis treatment. About 6,500 of these withdrawals are due to failure to thrive or other medical complications. Financial stress may contribute to the decision to withdraw from treatment of some of the 1,500 patients who withdraw for other reasons.

CBO assumes that enactment of H.R. 3511 would reduce the number of dialysis patients in extreme financial distress, because dialysis facilities that pay premiums for low-income patients would also be likely to write-off much of the cost-sharing obligations of those patients. As a result, CBO estimates that the number of deaths following voluntary withdrawal from dialysis treatment would decline by about 100 per year. However, because these survivors would nonetheless have high mortality rates, CBO estimates the net increase in the number of enrollees with ESRD would rise from about 75 in 1999 to 200 in 2008.

CBO estimates that Medicare will spend about \$40,000 per enrollee with ESRD in 1999. Therefore, Medicare spending for services furnished to dialysis patients would increase by \$3 million in 1999. Most of this spending would be for services covered by Part B, so Part B premium receipts from all Medicare patients enrolled in Part B would increase by almost \$1 million. Thus, net Medicare spending in 1999 would increase by \$2 million. Over the 1999–2003 period, gross Medicare spending would increase by \$25 million, and Part B premiums would rise by \$5 million, resulting in a net increase of \$20 million.

Pay-as-you-go considerations: Section 252 of the Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. The net changes in outlays and governmental receipts that are subject to pay-as-you-go procedures are shown in the following table. For the purposes of enforcing pay-as-you-go procedures, only the effects in the current year, the budget year, and the succeeding four years are counted.

[By fiscal year, in millions of dollars]

| | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|--------------------|------|------|------|------|------|------|------|------|------|------|------|
| Changes in outlays | 0 | 2 | 4 | 4 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |

Intergovernmental and private-sector impact: H.R. 3511 contains no private-sector or intergovernmental mandates as defined in the Unfunded Mandates Reform Act and would not affect the budgets of state, local, or tribal governments.

Estimate prepared by: Federal costs: Tom Bradley; impact on State, local, and tribal governments: Leo Lex; impact on the private sector: Bruce Vavrichek.

Estimate approved by: Paul N. Van de Water, Assistant Director for Budget Analysis.

V. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

A. Committee Oversight Findings and Recommendations

With respect to clause 2(1)(3)(A) of rule XI of the Rules of the House of Representatives, the Committee states that the Committee believed this action is necessary due to its oversight of the Medicare program. The Subcommittee on Health held a general hearing on health care fraud and abuse statutes on October 9, 1997.

B. Summary of Findings and Recommendations of the Government Operations Committee

With respect to clause 2(1)(3)(D) of rule XI of the Rules of the House of Representatives, the Committee states that no oversight findings or recommendations have been submitted by the Committee on Government Reform and Oversight regarding the subject of the bill.

C. Constitutional Authority Statement

With respect to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, relating to Constitutional Authority, the Committee states that the Committee's action in reporting the bill is derived from Article I of the Constitution, Section 8 ("The Congress shall have power to lay and collect taxes, duties, imposts and excises, to pay the debts and provide for the common defense and general welfare of the United States * * * .).

VI. CHANGES IN EXISTING LAW MADE BY THE BILL AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

PART A—GENERAL PROVISIONS

* * * * *

CIVIL MONETARY PENALTIES

| * * * * * * * * * * * * * * * * * * * |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (1) *** * * * * * * * * * * * (6) The term "remuneration" includes the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term "renumeration" does not include— (A) * * * [(B) any permissible waiver as specified in section 1128B(b)(3) or in regulations issued by the Secretary;] (B) any permissible practice described in any subparagraph of section 1128B(b)(3) or in regulations issued by the Secretary; * * * * * * * * * * GUIDANCE REGARDING APPLICATION OF HEALTH CARE FRAUD AND |
| (6) The term "remuneration" includes the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term "renumeration" does not include— (A) * * * [(B) any permissible waiver as specified in section 1128B(b)(3) or in regulations issued by the Secretary;] (B) any permissible practice described in any subparagraph of section 1128B(b)(3) or in regulations issued by the Secretary; * * * * * * * * * * * * * * * ** GUIDANCE REGARDING APPLICATION OF HEALTH CARE FRAUD AND |
| ance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term "renumeration" does not include— (A) * * * [(B) any permissible waiver as specified in section 1128B(b)(3) or in regulations issued by the Secretary;] (B) any permissible practice described in any subparagraph of section 1128B(b)(3) or in regulations issued by the Secretary; * * * * * * * * * * * * * * * * * * * |
| GUIDANCE REGARDING APPLICATION OF HEALTH CARE FRAUD AND |
| |
| |
| Sec. 1128D. (a) * * * (b) Advisory Opinions.— (1) * * * |
| (2) MATTERS SUBJECT TO ADVISORY OPINIONS.—The Secretary shall issue advisory opinions as to the following matters: (A) What constitutes prohibited remuneration within the meaning of section 1128B(b) or section 1128A(i)(6). |